K131187

5. 510(k) Summary

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: April 3, 2013
Applicant: Solana Surgical, LLC
6363 Poplar Ave, Suite 312
Memphis, TN 38119
Joe Clift (Contact)
(901) 818-1860

OCT 2 2 2013

Common Name:	Toe joint, lesser metatarsal (hemi-toe) prosthesis
Device Trade Name:	Lesser Metatarsal Head Implant System
Device Classification Name:	Toe joint metatarsal (hemi-toe) polymer prosthesis
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number:	21 CFR 888.3730
Product Code:	KWD
Predicate Device(s):	OsteoMed: K073065 Vilex: K102401

Device Description:

The Solana Surgical Implant is a one-piece device made of Cobalt Chromium (with titanium plasma spray coated stem) intended to replace the articulating surface of the metatarsal bone at the lesser metatarsal phalangeal (MTP) joint. The implant is available in a range of sizes (3) to match the geometry of the lesser metatarsal phalangeal joint. Design features include an articulating surface and a stem which extends proximally in the intramedullary canal of the distal lesser metatarsal. The design of the Solana Surgical implant is similar to the predicate devices. No new materials or processes are used in the development of this implant.

Indications for Use:
The Solana Surgical LLC, Lesser Metatarsal Head Implant System is intended for use as a hemi-arthroplasty implant for the metatarsophalangeal joint, for the treatment of degenerative and post-traumatic arthritis, hallux limitus, hallux valgus, hallux rigidus, and an unstable or painful metatarsophalangeal (MTP) joint. The device is intended for single use to be used with bone cement or press fit without bone cement.

Comparison to Predicate Device:

Similarities of the Solana Surgical device to its predicates include these devices being: intended for single use only, intended for surgical implantation longer than 30 days, system consisting of a series of implants, made of industry standard materials, with no new materials being introduced in the product, comparably sized, and indicated for the same uses.

An engineering analysis was performed to evaluate the mechanical strength of subject and predicate device implant stems.

The titanium plasma spray coating process as applied to the Solana Surgical device has been thoroughly evaluated for morphological and strength characteristics.

Based on the comparable materials used, indications for use, testing and analysis, the Solana Surgical device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 22, 2013

Solana Surgical, LLC
Mr. Joe Clift
Senior Vice President Quality and Regulatory
6363 Poplar Ave, Suite 312
Memphis, Tennessee 38119

Re: K131187
Trade/Device Name: Lesser Metatarsal Head Implant System
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: Class II
Product Code: KWD
Dated: September 6, 2013
Received: September 9, 2013

Dear Mr. Clift:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K131187
Device Name: Lesser Metatarsal Head Implant System
Indications for Use:

The Solana Surgical LLC, Lesser Metatarsal Head Implant System is intended for use as a hemi-arthroplasty implant for the metatarsophalangeal joint, for the treatment of degenerative and post-traumatic arthritis, hallux limitus, hallux valgus, hallux rigidus, and an unstable or painful metatarsophalangeal (MTP) joint.

The device is intended for single use to be used with bone cement or press fit without bone cement.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey E. Hanley, Ph.D.
Division of Orthopedic Devices